

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

In re Entresto (Sacubitril/Valsartan) Patent
Litigation

C.A. No. 20-2930-RGA

NOVARTIS PHARMACEUTICALS
CORPORATION,

Plaintiff,

v.

C.A. No. 19-2053-RGA

MSN PHARMACEUTICALS INC., MSN
LABORATORIES PRIVATE
LIMITED, MSN LIFE SCIENCES
PRIVATE LIMITED,

Defendants.

FINAL JUDGMENT

WHEREAS Plaintiff Novartis Pharmaceuticals Corporation (“Novartis”) in the above-captioned suit has asserted that Defendants MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited (collectively “MSN”) infringed claims 1-4 of Novartis’s U.S. Patent No. 8,101,659 (“’659 Patent”) (“Asserted Claims of the ’659 Patent”) by filing Abbreviated New Drug Application (“ANDA”) No. 213748;

WHEREAS Novartis has asserted that MSN’s generic sacubitril/valsartan products as described in MSN’s ANDA No. 213748 (“MSN’s ANDA Products”) infringe the Asserted Claims of the ’659 Patent;

WHEREAS the Court on July 21, 2023 entered final judgment that the Asserted Claims of the ’659 Patent were infringed and were not invalid for non-enablement or obviousness, but were invalid for lack of written description (20-md-2930, D.I. 1120);

WHEREAS Novartis appealed the Court's July 21, 2023 final judgment to the Federal Circuit in Appeal Nos. 23-2218 and 23-2221 (consolidated under Appeal No. 23-2218);

WHEREAS the Federal Circuit on January 10, 2025 issued an opinion and judgment in Novartis's favor (Appeal No. 23-2218, D.I. 106, 107) affirming the Court's holdings that the Asserted Claims of the '659 Patent were not invalid for non-enablement or obviousness, and reversing the Court's finding that the Asserted Claims were invalid for lack of written description, and the Federal Circuit has now issued the mandate in Appeal No. 23-2218;

WHEREAS the '659 Patent expired on January 15, 2025, but Novartis has been awarded under 21 U.S.C. § 355a(c) an additional marketing exclusivity period of six months after the date the patent expires and MSN's ANDA is subject to that pediatric exclusivity;

IT IS HEREBY ORDERED, DECREED, AND ADJUDGED:

1. Judgment is entered in Novartis's favor that MSN's filing of ANDA No. 213748, including any amendments or supplements thereto, infringed the Asserted Claims of the '659 Patent under 35 U.S.C. § 271(e)(2).
2. Judgment is entered in Novartis's favor that any use, sale, offer for sale, manufacture, and/or importation into the United States of MSN's ANDA Products during the '659 Patent's term would infringe the Asserted Claims of the '659 Patent.
3. Judgment is entered in Novartis's favor and against Defendants MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited that claims 1-4 of the '659 Patent were not proven to be invalid.
4. Defendants MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited, and their affiliates, subsidiaries, and each of

their officers, agents, servants and employees and those acting in privity or in concert with one or more of the MSN Defendants, are enjoined from commercial marketing and sale of MSN's ANDA Products until FDA resets the effective approval date of MSN's ANDA No. 213748 to no earlier than July 16, 2025, the date after the expiration of pediatric exclusivity awarded to Novartis pursuant to 21 U.S.C. § 355a. This injunction shall be effective immediately.

5. In accordance with 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of MSN's ANDA No. 213748 shall be no earlier than July 16, 2025, the date after the expiration of pediatric exclusivity awarded to Novartis pursuant to 21 U.S.C. § 355a.
6. This Court shall retain jurisdiction to resolve any remaining disputes arising from this case or out of this final judgment.
7. Each party shall bear its own costs and attorney fees.

/s/ Richard G. Andrews

UNITED STATES DISTRICT JUDGE